

REMARKS

This application contains Claims 1-206, the status of which is as follows:

- (a) Claims 7 and 11-15 are as originally filed.
- (b) Claims 56, 60-64, and 151, 153-177 were previously amended.
- (c) Claims 6, 10, 55, 59, and 152 have been currently amended.
- (d) Claims 205 and 206 are new.
- (e) Claims 1-5, 8, 9, 16-54, 57, 58, 65-150, and 178-204 have been canceled.

No new matter has been added. Reconsideration is respectfully requested.

Support For Amendments

Claims 6, 7, 55, and 56 were found to recited allowable subject matter, but were objected to by the Examiner for depending upon a rejected base claim. Claims 6 and 55 have been currently amended to recite the limitations of (cancelled) independent Claims 1 and 50 from which they respectively depended. Claims 7 and 56 depend from Claims 6 and 55, respectively. It is therefore submitted that Claims 6, 7, 55, and 56 are now in condition for allowance.

Claims 10 and 59 have been currently amended to specifically state that the heart to which the signals are adapted to be applied is a human heart. It is submitted that the specification as a whole is clearly directed towards treating a human subject. For example, the specification notes: "Such signals may be applied substantially continuously, or they may be applied only as needed, for example, at certain hours of the day or upon demand by the patient, when the patient needs a boost in cardiac output" (page 21, lines

19-21; PCT/IL99/00392, of which the present patent application is in the national phase). The applicant submits that it is inherent that the patient who would demand a boost in cardiac output is a human patient.

Claims 10 and 59 have also been currently amended to recite that the extended pacing signal has an overall duration that is "greater than 8 ms from a time of initiation of application of that portion of the signal that initiates action potential propagation . "This is broadly supported in the specification of the present patent application, for example, with reference to Fig. 3A:

As noted hereinabove, in order to generate action potentials in the heart, pacing pulses need have a duration of no more than 1-2 ms, whereas T_1 is several times that long, and T_2 is many times longer. Therefore, only a small, initial fraction of signal 60 is needed for actually pacing the heart, and the remainder of the energy in the signal is applied to increase the contractility. (page 17, lines 13-17)

Claims 10 and 59 have additionally been currently amended to recite that " the signal has an amplitude that is not sufficient for cardioversion." This amendment is supported in the specification as follows: "Preferably, the signal has an amplitude at least three times as great as a threshold for pacing the heart, but not sufficient for cardioversion ..." (page 11, lines 16-17).

Claim 152 has been currently amended to add the word "wherein."

Claims 205 and 206 are apparatus and method claims similar to currently-amended Claims 10 and 59, respectively, except that they replace the limitation of the extended pacing signal comprising a train of pulses with the limitation that the extended pacing signal comprises a single extended pulse. This amendment is supported in the specification, for example, as follows: "The pulse train preferably has a repetition frequency between 50 and 200 Hz (period between 5 and 20 ms), for maximal enhancement of hemodynamic function, and is superimposed on a DC offset. Other signals may also be used, however, for example: a single extended pulse, ..." (page 16, line 31 - page 17, line 3).

Mouchawar et al. (US 5,906,633)

Claims 1-5, 8, 9, 50-54, 57, 58, 151, 155, 164, 166, 172, 173, and 176 were rejected under 35 USC 102(e) as being anticipated by Mouchawar et al. (US 5,906,633). Of these claims, Claims 151, 155, 164, 166, 172, 173, and 176 are currently pending in this application.

The Examiner wrote that Mouchawar:

...provides a signal (40 Volts, 10-20 ms -- column 9) that will/can cause an action potential of the heart and is similar to the applicant's pulse length. Although Mouchawar calls his signal a 'cardioversion' signal, his signal will/can still cause an action potential and will still pace the heart and will not cause cardioversion in a larger sized heart. In addition, the particular type of heart (human, whale, mouse, etc.) and the signal level needed for pacing and cardioversion have not been claimed, only that the signal is 8 ms and is a "pace" signal. ...

Currently-amended independent Claims 10 and 59 were not rejected over Mouchawar. Nevertheless, it is noted that Claims 10 and 59 now recite (in addition to their other limitations) pacing a human heart with a signal having an amplitude that is not sufficient for cardioversion. This invention is not described in Mouchawar, and is not suggested by Mouchawar because the specification and claims of Mouchawar are directed towards apparatus for applying cardioverting shocks to a human patient. Applying a signal as claimed in Claims 10 and 59, which is not sufficient for cardioversion, is entirely unrelated to the teaching of Mouchawar.

The applicant respectfully submits that independent Claims 10 and 59 are patentable over Mouchawar. Claims 151, 155, 164, 166, 172, 173, and 176, which were rejected over Mouchawar but are dependent on Claims 10 or 59, directly or indirectly, are likewise submitted to be patentable over Mouchawar because they are of narrower scope than Claims 10 or 59.

Kroll et al. (US 5,978,703)

Claims 1-3, 5, 8-13, 50-52, 54, 57-62, 151, 155, 161, 164, 166, 168, 172, 173, and 175-177 were rejected under 35 USC 102(e) as being anticipated by Kroll et al. (US 5,978,703). Of these claims, Claims 10-13, 59-62, 151, 155, 161, 164, 166, 168, 172, 173, and 175-177 are currently pending in the present patent application.

In particular, Claims 10 and 59 were rejected as being anticipated by Kroll. The applicant respectfully submits that the 1-5 ms pulse width (Fig. 4) noted by the Examiner as being taught by Kroll does not anticipate the invention recited in currently-amended Claims 10 and 59 ("...the extended pacing signal having an overall duration greater than 8 ms..."). The example shown and described with reference to Fig. 4 of Kroll "...corresponds to a heart rate of 120 beats per minute" (column 4, lines 48-49), and

teaches applying a series of 50 V forcing pulses, having pulse durations of 1-5 ms, during each 500 ms cardiac cycle. The applicant additionally submits that there is no suggestion in Kroll to direct one to use pulse durations that are greater than 8 ms.

It is therefore submitted that independent Claims 10 and 59 are patentable over Kroll. Claims 11-13, 60-62, 151, 155, 161, 164, 166, 168, 172, 173, and 175-177, which were rejected over Kroll but are dependent on Claims 10 or 59, directly or indirectly, are likewise submitted to be patentable over Kroll because they are of narrower scope than Claims 10 or 59.

Mower (US 6,141,586)

Claims 1-5, 8-10, 12-15, 50-54, 57-59, 61-64, 151, 155, 161, 162, 164, 166, 168, 172, 173, and 177 were rejected under 35 USC 102(e) over Mower (US 6,141,586). Of these Claims, Claims 10, 12-15, 59, 61-64, 151, 155, 161, 162, 164, 166, 168, 172, 173, and 177 are currently pending in the present patent application.

In particular, Claims 10 and 59 were rejected over Mower. Currently-amended Claims 10 and 59 recite application of an extended pacing signal having an overall duration "...greater than 8 ms from a time of initiation of application of that portion of the signal that initiates action potential propagation..." Mower, by contrast, teaches:

FIG. 5 depicts a preferred embodiment of biphasic stimulation wherein a first stimulation phase, comprising low level, long duration anodal stimulation 502 having amplitude 504 and duration 506, is administered. This first stimulation phase is immediately followed by a second stimulation phase comprising cathodal stimulation 508 of conventional intensity and duration. In differing alternative embodiments, anodal stimulation 502 is: 1) at maximum subthreshold amplitude; 2) less than three volts; 3) of a

duration of approximately two to eight milliseconds; and/or 4) administered over 200 milliseconds post heart beat. Maximum subthreshold amplitude is understood to mean the maximum stimulation amplitude that can be administered without eliciting a contraction. In differing alternative embodiments, cathodal stimulation 508 is: 1) of a short duration; 2) approximately 0.3 to 1.5 milliseconds; 3) of a high amplitude; 4) in the approximate range of three to twenty volts; and/or 5) of a duration less than 0.3 millisecond and at a voltage greater than twenty volts. In a preferred embodiment, cathodal stimulation is about 0.8 millisecond. In the manner disclosed by these embodiments, as well as those alterations and modifications which can become obvious upon the reading of this specification, a maximum membrane potential without activation is achieved in the first phase of stimulation. (Column 8, lines 35-59; emphasis added)

The signal that Mower teaches as being 8 ms in duration is thus described by Mower as not producing activation of the heart. It is applied before the application of "a second stimulation phase comprising cathodal stimulation 508 of conventional intensity and duration" (column 8, lines 39-41). A suggested duration of the cathodal stimulation is "approximately 0.3 to 1.5 ms" (column 8, line 50).

The extended pacing pulse recited in currently-amended Claims 10 and 59 extends at least 8 ms from the time of initiation of application of that portion of the signal that initiates action potential propagation. (This does not exclude the possibility that a device built in accordance with embodiments of the present invention could also incorporate techniques described in Mower.)

It is therefore submitted that currently-amended Claims 10 and 59 are patentable over Mower. Claims 12-15, 61-64, 151, 155, 161, 162, 164, 166, 168, 172, 173, and 177, which were rejected over Mower but are dependent on Claims 10 or 59, directly or indirectly, are likewise submitted to be patentable over Mower because they are of narrower scope than Claims 10 or 59.

Ben-Haim et al. (WO 97/25098)

Claims 1-5, 8, and 9 were rejected under 35 USC 102(b) as being anticipated by Ben-Haim et al. (WO 97/25098). These Claims are no longer pending in the present patent application.

Rejections under 35 USC 102(e) and 35 USC 103

Claims 168 and 177 were rejected under 35 USC 102(e) or 35 USC 103(a) over Mouchawar. Claim 167 was rejected under 35 USC 102(e) or 35 USC 103(a) over Kroll. Claims 163 and 167 were rejected under 35 USC 102(e) or 35 USC 103(a) over Mower. Claim 174 was rejected under 35 USC 103(a) over Mouchawar (or Kroll or Mower). The applicant submits that this set of rejections is now moot, in light of the discussion above with respect to the patentability of currently-amended Claims 10 and 59, from which these Claims depend.

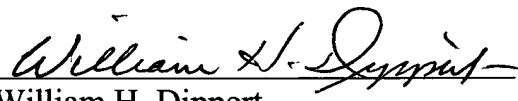
Elections/Restrictions

In an office action dated September 28, 2004, the applicant was required to elect species for prosecution on the merits, to which the Claims would be restricted if no generic Claim were finally held to be allowable. In the office action dated February 24, 2005, the examiner stated that Claims 152-154, 156-160, 165, and 169-171 are withdrawn from further consideration, there being no allowable generic or linking Claim. The applicant respectfully submits that these non-elected Claims directly or indirectly depend from allowable Claims 10 and 59, and should not be labeled "withdrawn." (As noted above, Claims 16-49, 65-150, and 178-204 have been canceled.)

In view of the above remarks, the applicant respectfully submits that all of the claims now pending in the present application are in condition for allowance. Notice to this effect is respectfully requested.

Respectfully submitted,

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